

Technology Readiness Levels (TRLs) in Healthcare

An example for medical devices

How close is an innovation to helping patients?

TRL 1-3

DISCOVERY

Could it work?

TRL 1



Observation of a need and problem

Researchers vet unmet need and define the problem and clinical opportunity of wearable ECG monitoring.

TRL 2



Ideation

Researchers create initial and iterative designs of wearable ECG monitor.

TRL 3



Early proof of concept

Initial low-fidelity prototypes created and early testing of components, designs and high-fidelity prototypes.

OUTPUTS Scientific and technical discoveries | Research papers | Patents | Early algorithms | New design concepts



TRL 4-6

DEVELOPMENT

Does it work?

TRL 4



Alpha prototype built and tested in a lab

First wearable ECG monitor developed and tested in the laboratory.

TRL 5



Technology validated in a relevant environment

Beta prototype ECG monitor tested on volunteers and compared with hospital ECG equipment.

TRL 6



Production prototype completed and technology demonstrated in a relevant environment

Device evaluated in clinics with cardiac patients.

OUTPUTS Beta and production prototypes | Feasibility studies | Pilot data and trials | Clinical validation data



TRL 7-9

ADOPTION

Can healthcare use it?

TRL 7



Used in real clinical workflows

Clinician uses the ECG monitor during treatment, collecting clinical effectiveness data for regulatory approval.

TRL 8



Regulatory approval and development readiness

The ECG wearable monitor has received approval (e.g., FDA clearance) and is ready for widespread adoption.

TRL 9



Routine clinical practice

The new ECG wearable monitor is used across multiple hospitals and improves clinical outcomes.

OUTPUTS Approved products | Commercialization | Service implementation | Population-level impact

